1.0 PURPOSE

This policy is designed to ensure that the Principal Investigator (PI) and Investigator of Record (IoR) has an adequate number of qualified pharmacy staff to conduct any Division of Acquired Immunodeficiency (DAIDS) funded and/or sponsored clinical trial.

2.0 SCOPE

This document represents the minimum acceptable standards for pharmacies at clinical research sites utilizing study product(s), and conducting DAIDS funded and/or sponsored clinical trials outside of the HIV/AIDS Clinical Trials Networks.

Additional requirements are likely to pertain at sites participating in multi-center clinical trials, such as those performed through the DAIDS-sponsored HIV/AIDS Clinical Trials Networks and/or clinical trials evaluating investigational agents.

3.0 BACKGROUND

Within DAIDS, the Pharmaceutical Affairs Branch (PAB) establishes and oversees policies for clinical research site pharmacies conducting DAIDS funded and/or sponsored domestic and international clinical trials. These policies include the development of standard operating procedures, quality assurance measures and accountability processes, prepared by the Pharmacist of Record, for the management of study products.

4.0 DEFINITIONS

Division of AIDS (DAIDS) sponsored – DAIDS is responsible for the management (including submission of the Investigational New Drug Application (IND) to FDA, and initiation of the study), and oversight for the trial.

Division of AIDS (DAIDS) funded – DAIDS is providing financial support for trial or study.

Investigator of Record (IoR) – The person responsible for the conduct of the clinical trial, at a clinical research site. This person is the signatory for the Form FDA 1572 (IND studies), or IoR Agreement (Non-IND studies).

Principal Investigator (PI) – The qualified person designated by the applicant institution to direct the research. PIs oversee the scientific and technical aspects of a grant and the day-

to-day management of the research.

Pharmacy – Any facility, building, or room used to perform one or more of the following functions: storage, preparation, dispensing, management of study products, (example: dispensary, drug storage unit, drug store).

Study products – Any drug, biologic, vaccine, radiopharmaceutical, item or device that are either provided for the study or identified in the protocol as being a study product.

Pharmacist of Record – A licensed/registered pharmacist who performs the day to day pharmacy activities and study product management including but not limited to the procurement, storage, preparation, dispensing and final disposition of study products for DAIDS funded and/or sponsored clinical trial(s) must be identified as the Pharmacist of Record.

For additional definitions see DAIDS glossary.

5.0 RESPONSIBILITIES

The PI and IoR are responsible for ensuring that there is a Pharmacist of Record at the site who is qualified by education, training and experience to conduct the trial.

The Pharmacist of Record is responsible for meeting the educational requirements needed to maintain licensure/registration.

The PI and IoR are responsible for ensuring that all clinical research site personnel involved in the conduct of any DAIDS funded and/or sponsored clinical trial are knowledgeable of the DAIDS standards for pharmacy personnel to ensure the proper conduct of the trial.

6.0 POLICY

6.1. The Pharmacist of Record must perform the day to day pharmacy activities and study product management including but not limited to the procurement, storage, inventory, preparation, dispensing, accountability, record keeping, labeling, handling and final disposition of study products for the trial.

6.1.1. Pharmacy staff can assist the Pharmacist of Record under his/her direct supervision.

6.1.2. The pharmacy staff must be qualified by pharmacy education, pharmacy training and pharmacy experience to perform his or her respective task(s).

6.2. The Pharmacist of Record must be available during clinic hours when study participants are present for their study visits.

6.2.1. When the Pharmacist of Record is absent a designated licensed/registered pharmacist must be present during the clinic hours when study participants are present for their study visits.

6.2.2. The designated licensed/registered pharmacist(s) must be trained in the conduct of the trial by the Pharmacist of Record to perform the activities of the Pharmacist of Record.

6.3. The Pharmacist(s) must comply with all applicable laws and regulations. This includes but is not limited to regulations concerning the import or export of study product.

7.0 REFERENCES

International Conference on Harmonisation, Guidance for Industry, E6 Good Clinical Practice: Consolidated Guidelines
http://www.fda.gov/oc/gcp/guidance.html

U.S. Code of Federal Regulations, Title 21, Part 312
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

Joint Commission International Accreditation Standards for Hospitals, 2002 by the Joint Commission on Accreditation of Healthcare Organizations

http://www.jointcommissioninternational.org/international.asp?durki=8086&site=109&return=7659

8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at: NIAIDOPCROPOLICYGROUP@mail.nih.gov

9.0 AVAILABILITY

This policy is available electronically at the following URL:
http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Default.htm

The signed original is maintained in the OPCRO policy office.

10.0 CHANGE SUMMARY

Version #	Date	Replaces	Date of Revision	Rationale for Revision/Retirement
2.0	20 DEC 06	1.0	20 DEC 06	DAIDS Final Review
1.0	14 JUL 06	N/A	N/A	N/A

11.0 APPENDICES

None.

12.0 APPROVAL

	Signature	**Program/Branch**	**Date**
Authorized By:	Richard Hafner		December 20, 2006
	Richard Hafner, MD Director	Office for Policy in Clinical Research Operations (OPCRO)	